K012644

JUL 2 9 2002

510(k) SUMMARY

Submitter's name: Surgical Instruments Servicing & Savings, Inc.
723 Curtis Court
Sisters, OR 97759
(541) 549-4164

Date summary prepared: August 10, 2001

Device name:

Proprietary name:	Reprocessed Trocars and Cannulas
Common or usual name:	Trocars and cannulas
Classification name:	Endoscope and accessories (876.1500).

Legally marketed device for substantial equivalence comparison:

The predicate device for each reprocessed trocar or cannula is the same product as provided by the original manufacturer.

Description of the device:

The devices that are the subject of this submission are used to open and maintain an entry port during endoscopic procedures. They are made of a variety of materials, sizes, and model numbers. They come from several different original equipment manufacturers as single use devices. Reprocessing includes cleaning, refurbishing, testing, packaging, and sterilization. It allows the trocars and cannulas to be used several times rather than just once.

Intended use of device:

Reprocessed trocars and cannulas are intended to open and maintain a port of entry during endoscopic procedures.

Technological characteristics:

The device features of the reprocessed trocars and cannulas are very similar. The materials and dimensions are identical. Both sets of products are provided sterile. The technical characteristics, method of use, and compatibility profile are also identical. The only difference is that the original products are sold for single use, while the reprocessed products can be used several times.

Testing conducted:

Each trocar and cannula is tested for functionality as part of the reprocessing procedures. Validation of the sterility protocol was also included in the submission.

Performance testing:

Comparative performance testing and clinical evaluations were not included as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2002

Surgical Instruments Service and Savings, Inc.
Robert S. McQuate
c/o R. S. McQuate and Associate, Inc.
3636 East Columbine Drive
Phoenix, Arizona 85032-5655

Re: K012644
Trade Name: Reprocessed Trocars and Cannulas
Regulation Number: 876.1500
Regulation Name: Endoscope and/or accessories
Regulatory Class: II
Product Code: KOG
Dated: May 21, 2002
Received: May 23, 2002

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012644

Device name: Reprocessed Trocars and Cannulas

Indications for Use: Reprocessed trocars and cannulas are intended to open and maintain a port of entry during endoscopic procedures.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012644